

Application No.: 09/800,240
Attorney Docket No. 057909-011000

REMARKS

Claims 1, 4, 7, 8 and 11-12 are pending, and claims 19-24 are added. By this amended, Applicant has canceled claims 2-3, 5-6, 9-10 and 13-18 without prejudice or disclaimer. Applicant reserve the right to pursue these canceled claims in a continuation or divisional application. By this amendment, Applicant has also amended claim 1, which now recites "A method of screening for a compound that modulates viral assembly and maturation comprising the steps of: maintaining an HIV-1 capsid protein in a solution; rapidly increasing salt concentration in said solution in the presence of a candidate compound or a control compound, wherein said HIV-1 capsid protein is capable of self-assembling upon said salt concentration increase in the presence of said control compound but not said candidate compound; and monitoring assembly of said HIV-1 capsid protein in the presence of said candidate compound, wherein an increase or decrease of assembly of said HIV-1 capsid protein in the presence of said candidate compound compared to said control compound indicates said candidate compound promotes or inhibits HIV-1 assembly respectively." This amendment is supported at least by Example 2 of the specification. Applicant has also amended claim 4 to replace the term "viral structural" with "HIV-1 capsid," and claim 12 to replace the term "viral" with "HIV-1 capsid protein," so that the amended claims have antecedent basis from claim 1. In addition, Applicant has amended claim 11 to make it dependent from claim 1. Furthermore, Applicant has added claims 19-24. Claims 19-24 are supported at least by Example 2 of the specification.

The amendments to the claims do not introduce new matter. Accordingly, Applicant respectfully requests the Examiner to enter these amendments.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

On page 1, the Office Action rejects claims 1-4 and 7-12 as being indefinite for reciting the terms "triggering assembly" and "monitoring viral assembly." Applicant respectfully traverses the rejection.

Applicant has canceled claims 2-3 and 9-10 without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Withdrawal of the rejection of these claims is therefore respectfully requested.

Applicant has amended claim 1 to replace the phrases "triggering assembly of said viral structural protein" and "contacting said viral structural protein with a candidate compound or a control compound that does not inhibit viral assembly" with "rapidly

BEST AVAILABLE COPY

Application No.: 09/800,240
Attorney Docket No.: 57909-011000

increasing salt concentration in said solution in the presence of a candidate compound or a control compound, wherein said HIV-1 capsid protein is capable of self-assembling upon said salt concentration increase in the presence of said control compound but not said candidate compound." Applicant believes that this amendment obviates the Examiner's rejection of the term "triggering assembly."

Applicant has also amended claim 1 to replace the phrase "monitoring viral assembly" with "monitoring assembly of said HIV-1 capsid protein in the presence of said candidate compound." Applicant submits that the phrase "monitoring assembly of said HIV-1 capsid protein" is definite, as the meaning of this phrase is apparent to one of ordinary skill in the art. In particular, Applicant submits that many well-known processes were available for monitoring viral assembly at the time the present application was filed. See, for example, Gross *et al.*, Eur. J. Biochem., 249:592-600 (1997). Therefore, claim 1 is definite even though the claim is not limited to any particular monitoring process. See MPEP §2173.04 ("Breadth of a claim is not to be equated with indefiniteness"). See also MPEP §2164.01 ("A patent need not teach, and preferably omits, what is well known in the art").

Based on the above reasons, Applicant submits that claim 1 satisfies the requirement under 35 U.S.C. § 112, second paragraph. Because claims 4, 7-8 and 11-12 depend from claim 1, Applicant submits that these claims also satisfy the requirement under 35 U.S.C. § 112, second paragraph. Withdrawal of the rejection of claims 1, 4, 7-8 and 11-12 is therefore respectfully requested.

On page 2, the Office Action rejects claims 13-18 as being indefinite for failing to recite the purpose of the claimed method and for reciting the phrase "assembling said viral structural protein." Applicant has canceled claims 13-18 without prejudice or disclaimer, thereby rendering the rejection of these claims moot.

Claim Rejection Under 35 U.S.C. § 112, First Paragraph

On pages 2-6, the Office Action rejects claims 1-4 and 7-18 for failing to satisfy the written description and enablement requirements under 35 U.S.C. § 112, first paragraph. Applicant respectfully traverses the rejection.

Applicant has canceled claims 2, 3, 9-10 and 13-18 without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Withdrawal of the rejection of these claims is therefore respectfully requested.

Applicant has amended claim 1 to replace the phrase "viral structural protein in a

soluble form" with "an HIV-1 capsid protein in a solution." Applicant believes that this amendment overcomes the Examiner's rejection. Withdrawal of the rejection of claim 1 is therefore respectfully requested.

Because claims 4, 7-8 and 11-12 depend from claim 1, Applicant submits that these claims also satisfy the written description and enablement requirements. Withdrawal of the rejection of these claims is also respectfully requested.

Claim Rejection Under 35 U.S.C. § 103(a)

On pages 11-12, the Office Action rejects claims 1-4 and 9-18 for being obvious over Gross *et al.* (1 997) (hereinafter "Gross") in view of Trono *et al.* (1987) (hereinafter "Trono"). Applicant respectfully traverses the rejection.

Applicant has canceled claims 2, 3, 9-10 and 13-18 without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Withdrawal of the rejection of these claims is therefore respectfully requested.

Applicant also submits that Gross and Trono, either alone or in combination, do not teach or suggest each and every element of claim 1. The Office Action contends that Gross teaches immature virion assembly "by diluting the purified protein(s) in a salt solution." However, as described in the section of "Materials and Methods," Gross used dialysis for virion assembly. See page 594, left column, of Gross. Specifically, Gross first diluted the protein stock with a storage buffer (30 mM Mes pH 6.0, 1 mM EDTA, 1 mM dithiothreitol without salt for CA and containing 0.5 M NaCl for CA-NC), and then dialyzed the diluted protein stock overnight against a salt solution. Because the CA stock is dialyzed against a solution with higher salt concentration, the CA stock is likely to become more concentrated, as opposed to being diluted.

In comparison, claim 1 of the present application features "rapidly increasing salt concentration" in a solution that comprises HIV-1 capsid protein. This process requires significantly less time than overnight dialysis. For instance, Example 2 and Figure 4 of the present application illustrate that in certain embodiments, virion assembly can be detected within seconds after salt increase. Accordingly, Applicant respectfully submits that Gross does not teach or suggest each and every element in claims 1.

The combination of Gross with Trono does not remedy this deficiency. Trono does not teach or suggest triggering virion assembly by rapidly increasing salt solution. Therefore, the combination of Trono and Gross does not teach or suggest each and every element in

Application No.: 09/800,240
Attorney Docket No.: 57909-011000

claim 1. See MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitation must be taught or suggested by the prior art"). Because claims 4 and 11-12 depend from claim 1, Applicant submits that the combination of Trono and Gross does not teach or suggest each and every element of these claims either.

Furthermore, Applicant submits that the Office Action has failed to provide evidence of a motivation to combine Gross with Trono. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. See *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). See also MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A statement that combination of the prior art to meet the claimed invention would have been within the ordinary skill in the art is not sufficient to establish a *prima facie* case of obviousness. See MPEP §2143.01. The Office Action has not produced any evidence showing any motivation to combine Gross and Trono.

On page 12, the Office Action states that "it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to test putative antivirals and regulators of assembly, as described by Trono *et al.* (1989), in the assembly system of Gross *et al.* (1997), since this would provide a facile method for identifying useful inhibitors or modulators of virion assembly." Applicant strongly disagrees with this statement. Applicant respectfully requests the Examiner to produce documentary proof for this statement. See MPEP §2144.03 (When relying on common knowledge in the art or "well known" in the art, the examiner should cite a reference in support of his/her position if the applicant traverses such an assertion).

Based on all of the above reasons, Applicant respectfully submits that the Office Action has failed to establish a *prima facie* case of obviousness against claims 1, 4 and 11-12. Accordingly, these claims are patentable over Gross and Trono. Withdrawal of the rejection of these claims is therefore respectfully requested.

On page 12-13, the Office Action rejects claims 7 and 8 for being obvious over Gross in view of Trono and Vlasuk *et al.* (1989) (hereinafter "Vlasuk"). Applicant respectfully traverses the rejection.

Claims 7 and 8 depend from claim 1. For the reasons set forth above, Applicant submits that Gross, Trono and Vlasuk, either alone or in combination, do not teach or suggest "rapidly increasing salt concentration" to trigger virion assembly. Accordingly, these references do not teach or suggest each and every element of claims 7 and 8. Moreover,

Application No.: 09/800,240
Attorney Docket No. G-7909-011000

Applicant submits that the Office Action has failed to provide any evidence showing a motivation to combine these references. Based on these reasons, Applicant respectfully submits that the Office Action has failed to establish a *prima facie* case of obviousness against claims 7 and 8. Withdrawal of the rejection of these claims is therefore respectfully requested.

Application No.: 09/800,240
Attorney Docket No. 057909-011000

CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Although Applicant believes that the amount of the attached fee is correct, the Commissioner is hereby authorized to charge any payment deficiency to deposit account number 19-2380 referring to attorney docket number 057909-011000.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,



Date: December 16, 2004

Scott J. Hawranek, Reg. No. 52,411
Nixon Peabody LLP
401 9th Street, N.W.
Suite 900
Washington, D.C. 20004
Tel. (202) 585-8000
Fax (202) 585-8080

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.